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News focus

Human cloning action stalled

The UN postponement of its decision on human cloning brought relief to stem cell researchers whose work may have been proscribed too. In spite of the ethical hurdles a growing number of countries are seeking to consider the potential in this field. **Michael Gross** reports.

'Human dignity is inviolable. To respect and protect is the duty of all state authority.' Thus begins the first article of the German constitution, the '*Grundgesetz*'. Many of the political debates of the last decades, from abortion to euthanasia, have been concerned with the interpretation of the concept of human dignity ('*Die Würde des Menschen*' – in a more literal translation: The dignity of the human being): when does this dignity begin and where does it end? Does an 8-cell blastocyst have human dignity, or a brain-dead patient whose metabolism is kept going by machines? Is the production of embryonic stem cells from blastocysts left over after IVF treatment a violation of human dignity?

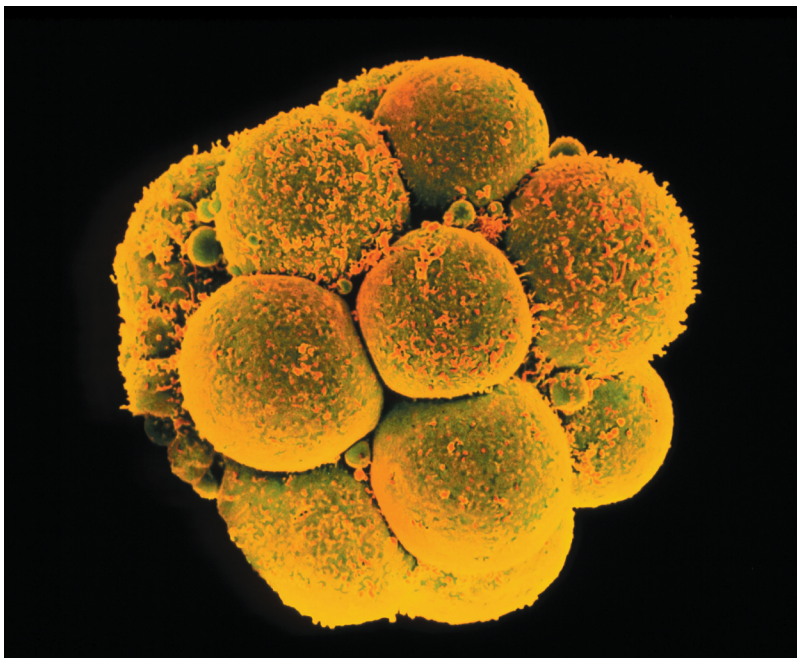
These questions are fundamentally important for all bioethics legislation in Germany, because article 1 allows no exception to the inviolability of human dignity. While article 2, which states the right to free development and right to life, keeps options open where the fundamental rights of others are affected (e.g. those of a woman seeking abortion), there is absolutely no messing with the dignity of human beings guaranteed by article 1.

The current stem cell legislation, passed in January 2002 by a cross-party majority of biosceptic backbenchers in the *Bundestag*, is based on the assumption that human dignity sets in when an egg is fertilized, no matter whether this happens *in vivo* or *in vitro*. As a consequence, German researchers are not allowed to produce embryonic stem cells, or even to collaborate with researchers abroad who produce them. They are only allowed to import stem cell lines generated before the first of January 2002, provided they obtain specific permission from an ethics council based at the Robert Koch Institut in Berlin. So far, the council has granted only five such permissions.

While the scientific community tends to disagree with the constitutional protection of undifferentiated cells as a matter of principle, it has learned to live with the current situation, which is regarded as a compromise that allows at least some research on imported stem cell lines to proceed over the next few years. A truce had been established between the sceptics who don't want any research based on embryos, and researchers who would ideally want to do a lot more than they are allowed to right now.

At the end of October, this truce was severely shaken by a speech of the justice minister, Brigitte Zypries (she replaced Herta Däubler-Gmelin who had mentioned Bush and Hitler in the same sentence during the build-up to the Iraq war). Even before Zypries addressed her audience at the Humboldt University, Berlin, a version of her manuscript circulated in media offices and started to send out shockwaves. The minister questioned whether an artificially fertilized egg can have human dignity. She argued that an egg or blastocyst does not per se have the ability to develop into a human being, as it requires the support of a woman willing to carry the pregnancy to term. As the state cannot force anybody to do that, the pre-implantation embryo has only a 'perspective on human dignity' which can be realized by a suitable woman, but not by the state.

Zypries made clear, however, that the embryos in question have



Postponed: A potential UN-backed restriction on human stem cell research has been delayed as an increasing number of countries are scrutinizing possible benefits from allowing such work to go ahead. (Picture: Science Photo Library.)

Spanish Steps to stem cell research

Governments everywhere are struggling to keep up with the changes in the science and bioethics of fertility and related issues. A remarkably sensible solution to the stem cell question has now been found in Spain.

Fifteen years ago, Felipe González's socialist government passed what was then a progressive law regulating *in vitro* fertilization, the Law of Assisted Reproduction (Ley de Reproducción Asistida). It ordered the clinics to store left-over embryos from IVF treatments for five years. As these left-over embryos started accumulating over the years, a national commission recommended in 1998 to allow their use for research, but the conservative government of José Maria Aznar's Partido Popular (PP) simply ignored that report. Only when a second official report, delivered last February, came to the same conclusion, the wheels of politics started moving.

Health minister Ana Pastor recently stated that the number of frozen IVF rejects in Spain is close to 200,000. Acknowledging that these embryos cannot be kept frozen forever, the government drew up a new legislation which essentially allows research – including production of new stem cell lines – on the already existing embryos, while blocking a similar build-up from happening in the future. When the law, which passed parliament in October, comes into force at the end of this year, both the IVF step and the implantation will be limited to three eggs per cycle. If there are still any leftovers, they will have to be kept for as long as the potential mother is biologically capable of carrying them to term.

While the parliamentary opposition voted against the restrictions on IVF procedures, it joined the scientific community in welcoming the prospect of research using 'old' blastocysts. Ironically, researchers in one of Europe's most catholic and conservative countries will soon be able to do research that is illegal in many places including Germany and the United States.

the right of life as stated in article 2 of the constitution. Unlike the right to human dignity, this right is not absolute, and can be balanced against other rights, such as the freedom of development of a potential mother, and the freedom of research. In a move to fence in the predictable reactions of religious critics, she also made clear that she opposed reproductive cloning and pre-implantation diagnostics.

Nevertheless, her speech created the biggest upheaval in the bioethics debate since the stem cell law was passed. Going beyond the usual exchange of arguments between pro- and anti-stem cell research fractions, commentators soon pointed to the tactical significance of the surprise move. It is known that Gerhard Schröder and the relevant members of his government are far from happy with the limitations that the 2002 law imposes on biotechnology. Research minister Edelgard Bulmahn and health minister Ulla Schmidt are known to support Zypries' interpretation. Wolfgang Clement, Schröder's 'super-minister' for economics and labour is so fervent a supporter of stem cell research that — in his previous function as head of a regional government — he even accompanied stem cell researcher Oliver Brüstle on a trip to Israel to foster research collaboration.

Thus, the unusual spectacle of a justice minister distancing herself from a law that is currently in force, far from being ridiculed as a faux-pas, was soon described as 'Schröder's test balloon,' as the weekly news magazine *Der Spiegel* put it. It appears that the chancellor wants to test whether the times are ready for a correction of the two-year-old stem cell law. After all, there has been a general election since the law was passed, and the general awareness of the potential benefits of stem cell research has been raised. Schröder, like many analysts, probably realizes that the time is not ripe yet for a more permissive legislation, but he sent out his minister to test out how much longer he may have to wait.

Meanwhile, his government expresses its research-friendly views on different fields far away from its sceptical parliament and population. This October, the United Nations have revived discussions of a possible convention to ban cloning, which had been started and then abandoned without result a year earlier. Over 40 countries, including the USA, have supported a proposal from Costa Rica, which would instate a comprehensive ban not only on reproductive cloning, but also on so-called therapeutic cloning, i.e. generating replacement tissues from embryonal stem cells. In February, the German parliament voted to demand that the foreign office supports a UN convention that bans both kinds of research.

The German UN delegation, however, has interpreted this mandate loosely in that it supports a two-step approach. It argues that a ban on reproductive cloning would easily find a broad consensus in the UN, while the question of therapeutic cloning would divide the assembly. Therefore, the German delegation is not backing the Costa Rican proposal, but the text proposed by Belgium banning only reproductive cloning and leaving the other uses of human embryo cells to national legislation. As a number of countries including the UK, Israel, and China are rigorously opposed to a blanket ban, the more restrictive proposal was seen as unlikely to succeed in any case.

On November 6th, the legal committee of the UN General Assembly might have voted on the Costa Rican proposal against the Belgian one. The show-down was averted, however, when the committee accepted by a narrow vote the proposal of Iran to defer the decision on any convention

against cloning by another two years. By the autumn of 2005, both the scientific and the political context of such a convention may be different. By then, the Bush administration, which had acted against the clear recommendation of its National Academy may have been replaced. And the German government may have managed to win the backing of its own parliament in this important question.

The German government also got a boost last month from a vote in the European parliament to allow European Union funds to be spent on stem cell research in spite of bitter opposition from some campaign groups. The move puts pressure on member governments to free between 40 and 50 million euros for studies to use cells from human embryos.

MEPs voted by 291 to 235 to support new quality and safety standards for 'the manipulation of tissues and cells' after intense lobbying by patient groups and medical researchers.

The highly divisive issue split the parliament down the middle earlier this year. However the landmark decision is not binding and the last word will remain with member states. They will ultimately decide whether to lift a moratorium that prevents cash from Brussels being spent on such experiments.

Sweden, Finland, Greece, the Netherlands and Britain allow harvesting stem cells from so-called supernumerary embryos — ones that are the result of *in vitro* fertilization — under certain conditions. Britain is the only EU country at present that allows the creation of embryos for stem cell procurement.

Some Catholic countries such as Italy, Portugal and Austria may continue to oppose the proposals. 'No country is forced to do anything they believe is wrong but ethical issues are matters for national parliaments to decide,' said David Bowe, a Labour MEP.

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Funding shake-up urged

Britain's system of funding university research is under fire as outdated. **Nigel Williams** reports.

The British government has made a commitment to increase spending on university research, but the mechanisms by which it assesses and allocates funds is drawing increasing criticism from a growing number of corners.

The UK's leading science academy has called on the government to launch a fundamental overhaul of university research funding, warning that the current system is burdensome, outdated and in need of reform.

The Royal Society says that universities are labouring under a funding structure established three decades ago in a 'simpler and very different world.' The society accuses the government of tinkering with small-scale reviews of research funding while failing to examine the whole.

The key to the problem, it argues, is the so-called dual support system, under which university research is funded through research councils, which fund direct project costs, and through the higher education funding councils, which distribute infrastructure money.

Meeting the demands of both strands burdens universities with 'huge human and institutional costs,' says the society's president, Robert May.

An analysis put the cost of the most recent research assessment exercise, conducted periodically since 1986 and used to share out infrastructure funds, at £360 million. Academics say money from the two funding sources are distributed in broadly the same way, despite requiring two separate processes. 'The time has come to stop rearranging the deck chairs on two entirely different ships which ultimately have the same direction,' says May.

The Royal Society's criticism follows a report by the vice-chancellors' organization, Universities UK, which attacked government moves to concentrate research funding in a few elite universities. It argued the move led to the loss of thousands of jobs without improving the quality of research. The substantial charitable sector funding biomedical research is also unhappy about suggestions that funding from charities will not be included as a factor in the research assessment exercise. The director of the Wellcome Trust, the largest British research funding charity, said: 'This will reduce the support received by many of the UK's most research-intensive universities and move funds away from biomedical sciences'.

'It is the fundamental belief of the Wellcome Trust that we fund university research in partnership with the government. We meet the full direct costs of the work - the costs of reagents and equipment, and the salaries of technical staff and many principal investigators. But we expect research environments — laboratories, libraries, personnel departments and so on — to be provided by the government,' says Walport.

'That is not to say that charities should not contribute to indirect costs. We have been enormous contributors to infrastructure, paying for buildings, staff and equipment,' he adds.

The combined assaults mean the government faces criticism of the proposed strategy on university research and of the mechanism required to fund it. Lord May also criticizes the research assessment exercise, saying it has become more burdensome and bureaucratic. He said that, while initially it proved effective in prompting a flurry of long-postponed research, it has now 'been perverted by many into a one-dimensional totem of the prestige of a university department, and ultimately of the institution itself.' He says the exercise 'has also promoted behaviours that play to the rules of the game, which may be different from those which serve research excellence'.

'Funding councils are between a rock and a hard place. They do not have enough money to sustain a world-class science base. Such sustainability will be reached only through consistent investment from government in partnership with the charities,' says Walport.